



Zimmer New Zealand Limited

PO Box 9628, Newmarket
210 Khyber Pass Rd, Grafton
Auckland 1149
Phone +64 9 368 1490
Fax +64 9 368 5360
www.zimmer.co.nz

10 October 2012

HAZARD ALERT

DUROM® Acetabular Component (Metal on Metal) For Hip Replacement.

Dear Surgeon,

Zimmer New Zealand Ltd ('Zimmer'), after consultation with Medsafe Ministry of Health, wishes to advise you of a Hazard Alert for the Durom Acetabular Component.

Please note that the Durom Acetabular Component was withdrawn from the Australian and New Zealand markets with effect from 30 June 2011. This was due to the substantial decline in demand for metal-on-metal articulations noted over recent years.

The latest analysis of data in the Australian National Joint Replacements Registry (NJRR) has identified a cumulative revision rate of 9.6% at 7 years in resurfacing applications and 6.8% at 5 years for Total Conventional Hip Replacement for the Durom Acetabular Component

Actions required from you:

1. Please note the contents of the alert and contact your patients who have been implanted with Durom Acetabular Components to advise them of this alert.
2. Please complete the attached Certificate of Acknowledgement and return by fax to the attention of **George Otero, Regulatory Affairs Manager, ANZ at Zimmer on Fax #: (09) 368 5360.**
3. Surgeons are advised to implement appropriate follow-up protocols for their patients. The follow-up that any surgeon or institution decides to adopt must be weighed against case-specific factors to determine which steps to take in the face of risks and consequences.

Management Recommendations for Patients with Metal on Metal Hip Replacement Implants.